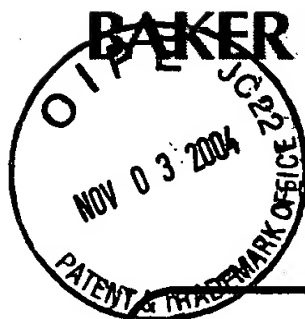


1643

Jh

BAKER BOTTS LLP



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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	09/320,767
	Filing Date	May 27, 1999
	First Named Inventor	Giannoukakis
	Group Art Unit	1643
	Examiner Name	Angell, J.
Total Number of Pages in This Submission	Attorney Docket Number	A32362(072396.0174)

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1449 Form References cited on IDS
Remarks <input type="checkbox"/>		

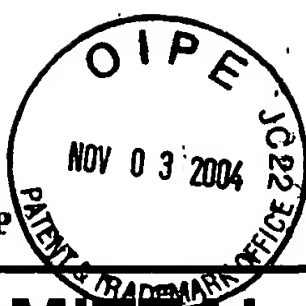
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	BakerBotts-LLP 30 Rockefeller Plaza New York, NY 10112
Signature	 Att Name: Rochelle K. Seide PTO Reg: 32,300
Date	November 1, 2004

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this date: November 1, 2004			
Typed or printed name	Rochelle K. Seide		
Signature		Date	November 1, 2004

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 0)

Complete if Known

Application Number	09/320,767
Filing Date	May 27, 1999
First Named Inventor	Giannoukakis
Examiner Name	Angell, J.
Art Unit	1643
Attorney Docket No.	A32362(072396.0174)

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None
☐ Deposit Account:
 Deposit
Account
Number
Deposit
Account
Name

02-4377

Baker Botts LLP

The Commissioner is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee required under 37CFR 1.16 and 1.17☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
SUBTOTAL (1)					(\$ 0)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims - 20 = X = 0
 Independent Claims - 3 = X = 0
 Multiple Dependent =

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1202	18	2202	9	Claims in excess of 20	
1201	86	2201	43	Independent claims in excess of 3	
1203	290	2203	145	Multiple dependent claim, if not paid	
1204	86	2204	43	** Reissue independent claims over original patent	
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)					(\$ 0)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 0)

SUBMITTED BY

(Complete if applicable)

Name (Print/Type)

Rochelle K. Seide

Registration No.
(Attorney/Agent)

32,300

Telephone 212 408 2500

Signature

Rochelle K. Seide

Date

November 1, 2004



Atty. Docket No. A32362 (072396.0174)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Giannoukakis *et al.*
Serial No. : 09/320,767 Examiner : Angell, J.
Filed : May 27, 1999 Group Art Unit: 1635
For : GENE TRANSFER TO PANCREATIC CELLS FOR
PREVENTION OF ISLET DYSFUNCTION

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

November 1, 2004,

Date of Deposit

Rockelle K. Seide

Attorney Name

Rockelle K. Seide

Signature

32,300

PTO Registration No.

November 1, 2004

Date of Signature

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In supplement to the Information Disclosure Statement filed on December 17, 1999, and pursuant to the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants respectfully request that the documents listed herein and on the accompanying PTO Form

1449 be considered by the Examiner and made of record in the U.S. Patent and Trademark Office.

The publications contained herein are identified as number 49-65 to distinguish it from the 48 publications previously disclosed in the above-identified application. The citations listed below are also listed in the accompanying PTO Form 1449.

49. United States Patent No. 6,268,194 by Karin, et al, issued July 31, 2001. IKB kinase and methods of using same.

50. International Search report dated December 1, 2000, for Application No. 09/580,801, (PCT/US00/14799) filed on May, 30, 2000.

51. Verma, I. M. (2000). Gene therapy: beyond 2000. *Mol Ther* 1, 493.

52. Giannoukakis, N., Mi, Z., Gambotto, A., Eramo, A., Ricordi, C., Trucco, M., and Robbins, P. (1999). Infection of intact human islets by a lentiviral vector. *Gene Ther* 6, 1545-1551.

53. Giannoukakis, N., Rudert, W. A., Ghivizzani, S. C., Gambotto, A., Ricordi, C., Trucco, M., and Robbins, P. D. (1999). Adenoviral gene transfer of the interleukin-1 receptor antagonist protein to human islets prevents IL-1beta-induced beta-cell impairment and activation of islet cell apoptosis in vitro. *Diabetes* 48, 1730-1736.

54. Giannoukakis, N., Rudert, W. A., Robbins, P. D., and Trucco, M. (1999). Targeting autoimmune diabetes with gene therapy. *Diabetes* 48, 2107-2121.

55. Grey, S. T., Arvelo, M. B., Hasenkamp, W. M., Bach, F. H., and Ferran, C. (1999). Adenovirus-mediated gene transfer of the anti-apoptotic protein A20 in rodent islets inhibits IL-1 beta-induced NO release. *Transplant Proc* 31, 789.

56. Anderson, W. F. (1998). Human gene therapy. *Nature* 392(6679 Suppl), 25-30.

57. Harrison, M., Dunger, A. M., Berg, S., Mabley, J., John, N., Green, M. H., and Green, I. C. (1998). Growth factor protection against cytokine-induced apoptosis in neonatal rat islets of Langerhans: role of Fas. *FEBS Lett* 435, 207-210.

58. Iwahashi, H., Itoh, N., Yamagata, K., Imagawa, A., Nakajima, H., Tomita, K., Moriwaki, M., Waguri, M., Yamamoto, K., Miyagawa, J., *et al.* (1998). Molecular mechanisms of pancreatic beta-cell destruction in autoimmune diabetes: potential targets for preventive therapy. *Cytokines Cell Mol Ther* 4, 45-51.
59. Loweth, A. C., Williams, G. T., James, R. F., Scarpello, J. H., and Morgan, N. G. (1998). Human islets of Langerhans express Fas ligand and undergo apoptosis in response to interleukin-1beta and Fas ligation. *Diabetes* 47, 727-732.
60. International Patent Application No. WO 9730083 by Erran, C., and Bach, F. H., published on August 21, 1997. Gene therapy of endothelial cells with anti-apoptotic proteins for transplantation and inflammatory conditions.
61. Verma, I. M., and Somia, N. (1997). Gene therapy -- promises, problems and prospects. *Nature* 389, 239-242.
62. Crystal, R. G. (1995). Transfer of genes to humans: early lessons and obstacles to success. *Science* 270, 404-410.
63. Welsh, N., Bendtzen, K., and Welsh, M. (1995). Expression of an insulin/interleukin-1 receptor antagonist hybrid gene in insulin-producing cell lines (HIT-T15 and NIT-1) confers resistance against interleukin-1-induced nitric oxide production. *J Clin Invest* 95, 1717-1722.
64. Evans, C. H., and Robbins, P. D. (1994). The interleukin-1 receptor antagonist and its delivery by gene transfer. *Receptor* 4, 9-15.
65. International Patent Application No. WO 9212724 by Eizirik, D. L., and Sandler, S. W., Published on August 6, 1992. Method of preventing and treating insulin dependent diabetes mellitus.

Copies of listed references are enclosed with the exception of document numbers 56, 58 and 64. These references will be provided to the Patent Office once they are available. Reference numbers 52-55, 57-60, and 63-65 are cited in the enclosed International Search Report. The submission of this Supplemental Information Disclosure Statement does not represent that a search has been made or that no better art exists, and does not constitute an admission that any of the listed documents are material or

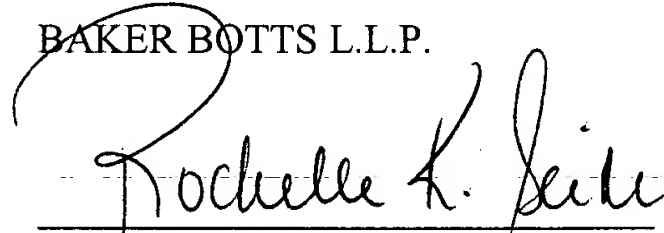
constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed document, should this document be applied against the claims of the present application.

Applicants do not believe that a fee is required. However, if any fee is required in connection with this communication or any overpayment has been made, please charge any deficiency or credit any overpayment to Deposit Account No. 02-4377. Duplicate copies of this communication are enclosed.

Respectfully submitted,

BAKER BOTTS L.L.P.

A handwritten signature in black ink, reading "Rochelle K. Seide". The signature is written in a cursive style with a large, looping initial "R".

Rochelle K. Seide
Patent Office Reg. No. 32,300

30 Rockefeller Plaza
44th Floor
New York, NY 10112
(212) 408-2626 direct dial

Attorney for Applicants

Enclosures

Form PTO-1449 U.S. Department of Commerce
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.
A32362
072396.0174

Serial No.
09/320,767

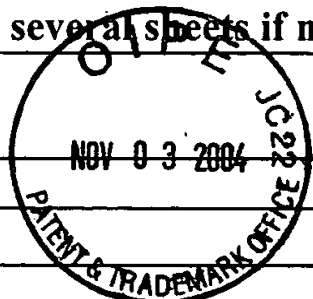
**INFORMATION DISCLOSURE
STATEMENT
BY APPLICANT**

(Use several sheets if necessary)

Applicant
Giannoukakis et al.

Filing Date
May 27, 1999

Group
1643



U.S. PATENT DOCUMENTS

*Ex am. Init.	Document No.	Date	Name	Class	Subclass	Filing Date if Appropriate
49	6 2 6 8 1 9 4	7/31/01	Karin et al.			

FOREIGN PATENT DOCUMENT

Document No.	Date	Country	Class	SubClass	Translator Yes No
60/ 9 7 3 0 0 8 3	8/21/97	WO			
65/ 9 2 1 2 7 2 4	8/6/92	WO			

OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)

50/	International Search report dated December 1, 2000, for Application No. 09/580,801, (PCT/US00/14799) filed on May, 30, 2000.
51/	Verma, I. M. (2000). Gene therapy: beyond 2000. <i>Mol Ther</i> 1, 493.
52/	Giannoukakis, N., Mi, Z., Gambotto, A., Eramo, A., Ricordi, C., Trucco, M., and Robbins, P. (1999). Infection of intact human islets by a lentiviral vector. <i>Gene Ther</i> 6, 1545-1551.
53/	Giannoukakis, N., Rudert, W. A., Ghivizzani, S. C., Gambotto, A., Ricordi, C., Trucco, M., and Robbins, P. D. (1999). Adenoviral gene transfer of the interleukin-1 receptor antagonist protein to human islets prevents IL-1beta-induced beta-cell impairment and activation of islet cell apoptosis in vitro. <i>Diabetes</i> 48, 1730-1736.
54/	Giannoukakis, N., Rudert, W. A., Robbins, P. D., and Trucco, M. (1999). Targeting autoimmune diabetes with gene therapy. <i>Diabetes</i> 48, 2107-2121.
55/	Grey, S. T., Arvelo, M. B., Hasenkamp, W. M., Bach, F. H., and Ferran, C. (1999). Adenovirus-mediated gene transfer of the anti-apoptotic protein A20 in rodent islets inhibits IL-1 beta-induced NO release. <i>Transplant Proc</i> 31, 789.
56/	Anderson, W. F. (1998). Human gene therapy. <i>Nature</i> 392, (6679 Suppl) 25-30.

Examiner

Date Considered

* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[illegible]

Date Considered

502878